IV. Claim 34, drawn to antisense to CA125, classifiable in class 536, subclasses 24.36 and 24.5.

Responsive to the Requirement for restriction, Applicants elect to prosecute the invention of group I, with traverse, Claims 1-19, 27, and 30-33 drawn to a polypeptide composition. Additionally, Applicant is required under 35 U.S.C § 121 to elect a single disclosed species for prosecution on the merits to which claims shall be restricted if no generic claim is finally held to be allowable. "Specifically, if Group I is elected above, application is required to pick a single combination of amino acid sequences for examination on the merits."

Applicants respectfully request reconsideration of the Requirement for Restriction, or in the alternative, modification of the Restriction Requirement to allow prosecution of more than one group of Claims designated by the Examiner in the present Application, for the reasons provided as follows.

Under 35 U.S.C § 121 "two or more independent and distinct inventions . . . in one Application may . . . be restricted to one of the inventions." Inventions are "independent" if "there is no disclosed relationship between the two or more subjects disclosed" (MPEP 802.01). The term "distinct" means that "two or more subjects as disclosed are related . . . but are capable of separate manufacture, use or sale as claimed, AND ARE PATENTABLE OVER EACH OTHER" (MPEP 802.01) (emphasis in original). However, even with patentably distinct inventions, restriction is not required unless one of the following reasons appear (MPEP 808.02):

1. Separate classification
2. Separate status in the art; or
3. Different field of search.

Further, under patent Office Examining Procedures, "[i]f the Search and Examination of an entire Application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to distinct or independent inventions" (MPEP 803, Rev. 8, May 1988) (emphasis added).

The Examiner's assertions to the contrary notwithstanding, Applicants respectfully

submit that conjoint examination and inclusion of all of the Clams of the present Application would not present an undue burden on the Examiner, and accordingly, withdrawal of the Requirement for Restriction, or, at the least, modification to include the Claims drawn to Group I and Group II is in order.

With respect to the requirement to elect a single species for examination on the merits, Applicants respectfully traverse this requirement for the following reasons:

I. Claim 1(b) providing the multiple repeat domains does not include a genus species relationship

Claim 1(b) relates to a multiple repeat domain. A CA125 molecule can include a variety, if not all of the repeats in a single molecule. SEQ ID NO: 162 which show the recombinant molecule has been marked up as Appendix Tab A, to show the multiple repeats present in a single molecule. Claims to be restricted to different species must be mutually exclusive. The general test as to when claims are restricted respectively to different species is the fact that one claim recites limitations which under the disclosure are found in a first species, but not in a second, while a second claim recites limitations disclosed only from the second species and not the first. MPEP § 12.0[3[c]. As can be seen from an inspection of the recombinant molecule shown in SEQ ID NO: 162, CA125 molecule within the scope of claim 1(b) may have multiple repeat domains which are not mutually exclusive. Consequently, Applicants respectfully request examination on the multiple repeat domains as claimed.

This requirement to elect a single combination of repeats violates the basic right of the Applicants to claim his invention as he chooses. In re Weber, 580 F.2d 455 (USCC 1978).

II. Restriction is not appropriate if the claims are directed to substantially the same molecule

Species are patentably distinct when they are related, but they are capable of separate manufacture and are patentable (novel and nonobvious) over each other. The multiple repeat domains contain multiple repeats wherein each repeat unit has five genomic exons. The variation in repeats set out in Claim 1 (b) are 82% identical and thus present related chemical compounds. The repeat domain is a sequence of 156 amino acids which are repeated multiple times within a discrete portion of the CA125 protein. The repeat domain has its own function and combines with the other domains to provide the overall function of the protein. The

designated exons in the repeat domain can vary, but, this variance is minimal. Importantly, when the nucleic acids are expressed they form a CA125 protein.

Restriction is not appropriate if claims are directed to the same protein.

Applicant hereby elects the following species, with traverse, for prosecution on the merits.

1. A CA125 molecule, comprising:

(a) an extracellular amino terminal domain, comprising 5 genomic exons, wherein exon 1 comprises amino acids #1-33 of SEQ ID NO: 299, exon 2 comprises amino acids #34-1593 of SEQ ID NO: 299, exon 3 comprises amino acids #1594-1605 of SEQ ID NO: 299, exon 4 comprises amino acids #1606-1617 of SEQ ID NO: 299, and exon 5 comprises amino acids #1618-1637 of SEQ ID NO: 299;

(b) a multiple repeat domain, wherein each repeat unit comprises 5 genomic exons, wherein exon 1 comprises amino acids #1-42 in any of SEQ ID NO: 186; exon 2 comprises amino acids #43-65 in any of SEQ ID NO: 197; exon 3 comprises amino acids #66-123 in any of SEQ ID NO: 244; exon 4 comprises amino acids #124-135 in any of SEQ ID NO: 271; exon 5 comprises amino acids #136-156 in any of SEQ ID NO: 287; and

(c) a carboxy terminal domain comprising a transmembrane anchor with a short cytoplasmic domain, and further comprising 9 genomic exons, wherein exon 1 comprises amino acids #1-11 of SEQ ID NO: 300; exon 2 comprises amino acids #12-33 of SEQ ID NO: 300; exon 3 comprises amino acids #34-82 of SEQ ID NO: 300; exon 4 comprises amino acids #83-133 of SEQ ID NO: 300; exon 5 comprises amino acids #134-156 of SEQ ID NO: 300; exon 6 comprises amino acids #157-212 of SEQ ID NO: 300; exon 7 comprises amino acids #213-225 of SEQ ID NO: 300; exon 8 comprises amino acids #226-253 of SEQ ID NO: 300; exon 1 comprises amino acids #254-284 of SEQ ID NO: 300.

In view of the above, withdrawal of the Requirement for the Restriction is requested, and an early action on the merits of the Claims is courteously solicited.

Respectfully Submitted,

BUTLER, SNOW, O'MARA,
STEVENS & CANNADA

Date: 1-13-04

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail, postage prepaid, on 1-13-04, in a package addressed to: Mail Stop: Art Unit 1635, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Lori Wood
LORI WOOD

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7590 11/13/2003

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ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 11/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Notice of Non-Responsive Amendment

Applicant's Amendment, filed September 15, 2003 is acknowledged.

Election/Restrictions

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's election without traverse of Group I (claims 1-19, 27, and 30-33) is acknowledged. With respect to election of a species, Applicant's election without traverse of the amino acid sequence set out in SEQ ID NO:162 is acknowledged. However, this election of species is non-responsive to the previous Restriction Requirement, filed June 10, 2003 for the following deficiencies: In the previous Restriction Requirement, at page 3, last paragraph, it is explicitly stated that, "Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, if Group I is elected above, Applicant is required to pick a single combination of amino acid sequences for examination on the merits" [emphasis added]. Applicant's election of SEQ ID NO:162 is not a single combination of amino acid sequences for examination, but is instead, the entire coding region of the CA125 gene.

Applicants are required to pick a single combination of amino acid sequences for examination on the merits.

Applicant is reminded, should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Since the reply filed on June 11, 2003 appears to be *bona fide*, applicant is given a TIME PERIOD of **ONE (1) MONTH** or **THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to submit an amendment in compliance with 37 CFR 1.121 in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. If

attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
November 7, 2003

KAREN A. LACOURCIERE, PH.D
PRIMARY EXAMINER

multiple repeat domain

```
                                  164
A TVPFMVPFTL NFTITNLQYE EDMRHPGSRK
                                                  195
12101  FNATERELQG LLKPLFRNSS LEYLYSGCRL ASLRPEKDSS AMAVDAICTH
                                222                          250
12151  RPDPEDLGLD RERLYWELSN LTNGIQELGP YTLDRNSLYV NGFTHRSSMP
                          278                          191
12201  TTSTPGTSTV DVGTSGTPSS SPSPTAAGPL LMPFTLNFTI TNLQYEEDMR
                                                197
12251  RTGSRKFNTM ESVLQGLLKP LFKNTSVGPL YSGCRLTLLR PEKDGAATGV
                          223
12301  DAICTHRLDP KSPGLNREQL YWELSKLTND IEELGPYTLD RNSLYVNGFT
                262                   279
12351  HQSSVSTTST PGTSTVDLRT SGTPSSLSSP TIMAAGPLLV PFTLNFTITN
                     173                          201
12401  LQYGEDMGHP GSRKFNTTER VLQGLLGPIF KNTSVGPLYS GCRLTSLRSE
                          234
12451  KDGAATGVDA ICTHHLDPKS PGLNRERLYW ELSQLTNGIK ELGPYTLDRN
                     252                   280
12501  SLYVNGFTHR TSVPTSSTPG TSTVDLGTSG TPFSLPSPAT AGPLLVLFTL
                176                                202
12551  NFTITNLKYE EDMHRPGSRK FNTTERVLQT LLGPMFKNTS VGLLYSGCRL
                               235
12601  TLLRSEKDGA ATGVDAICTH RLDPKSPGLD REQLYWELSQ LTNGIKELGP
                          267                          281
12651  YTLDRNSLYV NGFTHWIPVP TSSTPGTSTV DLGSGTPSSL PSPTAAGPLL
                182                                202
12701  VPFTLNFTIT NLQYEEDMHH PGSRKFNTTE RVLQGLLGPM FKNTSVGLLY
                               236
12751  SGCRLTLLRS EKDGAATGVD AICTHRLDPK SPGVDREQLY WELSQLTNGI
                          263                          283
12801  KELGPYTLDR NSLYVNGFTH QTSAPNTSTP GTSTVDLGTS GTPSSLPSPT
                170
12851  SAGPLLVPFT LNFTITNLQY EEDMRHPGSR KFNTTERVLQ GLLKPLFKST
                198                          236
12901  SVGPLYSGCR LTLLRSEKDG AATGVDAICT HRLDPKSPGV DREQLYWELS
                               263                          283
12951  QLTNGIKELG PYTLDRNSLY VNGFTHQTSA PNTSTPGTST VDLGTSGTPS
                          183
13001  SLPSPTSAGP LLVPFTLNFT ITNLQYEEDM HHPGSRKFNT TERVLQGLLG
                202                                240
13051  PMFKNTSVGL LYSGCRLTLL RPEKNGAATG MDAICSHRLD PKSPGLNREQ
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13101  LYWELSQLTH GIKELGPYTL DRNSLYVNGF THRSSVAPTS TPGTSTVDLG
                283                    165
13151  TSGTPSSLPS PTTAVPLLVP FTLNFTITNL QYGEDMRHPG SRKFNTTERV
                          205
13201  LQGLLGPLFK NSSVGPLYSG CRLISLRSEK DGAATGVDAI CTHHLNPQSP
                     238                          257
13251  GLDREQLYWQ LSQMTNGIKE LGPYTLDRNS LYVNGFTHRS SGLTTSTPWT
                285                         177
13301  STVDLGTSGT PSPVPSPTTA GPLLVPFTLN FTITNLQYEE DMHRPGSRKF
                               207
13351  NATERVLQGL LSPIFKNSSV GPLYSGCRLT SLRPEKDGAA TGMDAVCLYH
                          227                          265
13401  PNPKRPGLDR EQLYWELSQL THNITELGPY SLDRDSLYVN GFTHQNSVPT
                     286                    186
13451  TSTPGTSTVY WATTGTPSSF PGHTEPGPLL IPFTFNFTIT NLHYEENMQH
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13701 AATGVDTICT HRVDPIGPGL DRERLYWELS QLTNSITELG PYTLDRDSLY

13751 VNGFNPRSSV PTTSTPGTST VHLATSGTPS SLPGHTAPVP LLIPFTLNFT

13801 ITNLHYEENM QHPGSRKFNT TERVLQGLLK PLFKNTSVGP LYSGCRLTLL

13851 RPEKHEAATG VDTICTHRVD PIGPGLDREX LYWELSXLTX XIXELGPYXL

13901 DRXSLYVNGF XXXXXXXXTS TPGTSXVXLX TSGTPXXXPX XTSAGPLLVP

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14001 CRLTLLRPEK MGAATGMDAI CSNRLLPKSP GLDREQLYWE LSQLTHSITE

14051 LGPYTLDRNS LYVNGFTHRS SVAPTSTPGT STVDLGTSGT PSSLPSPTTA

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14151 GPLYSGCRLI SLRSEKDGAA TGVDAICTHH LNPQSPGLDR EQLYWQLSQM

14201 TNGIKELGPY TLDRNSLYVN GFTHRSSGLT TSTPWTSTVD LGTSGTPSPV

14251 PSPTTAGPLL VPFTLNFTIT NLQYEEDMHR PGSRKFNATE RVLQGLLSPI

14301 FKNSSVGPLY SGCRLTSLRP EKDGAATGMD AVCLYHPNPK RPGLDREQLY

14351 WELSQLTHNI TELGPYSLDR DSLYVNGFTH QSSMTTTRTP DTSTMHLATS

14401 RTPASLSGPT TASPLLVLFT INCTITNLQY EEDMRRTGSR KFNTMESVLQ

14451 GLLKPLFKNT SVGPLYSGCR LTLLRPKKDG AATGVDAICT HRLDPKSPGL

14501 NREQLYWELS KLTNDIEELG PYTLDRNSLY VNGFTHQSSV STTSTPGTST

14551 VDLRTSGTPS SLSSPTIMXX XPLLXPFTLN FTITNLXYEE XMXXPGSRKF

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14701 TSTPGTSTVH LATSGTPSSL PGHTXXXPLL XPFTLNFTIT NLXYEEXMXX

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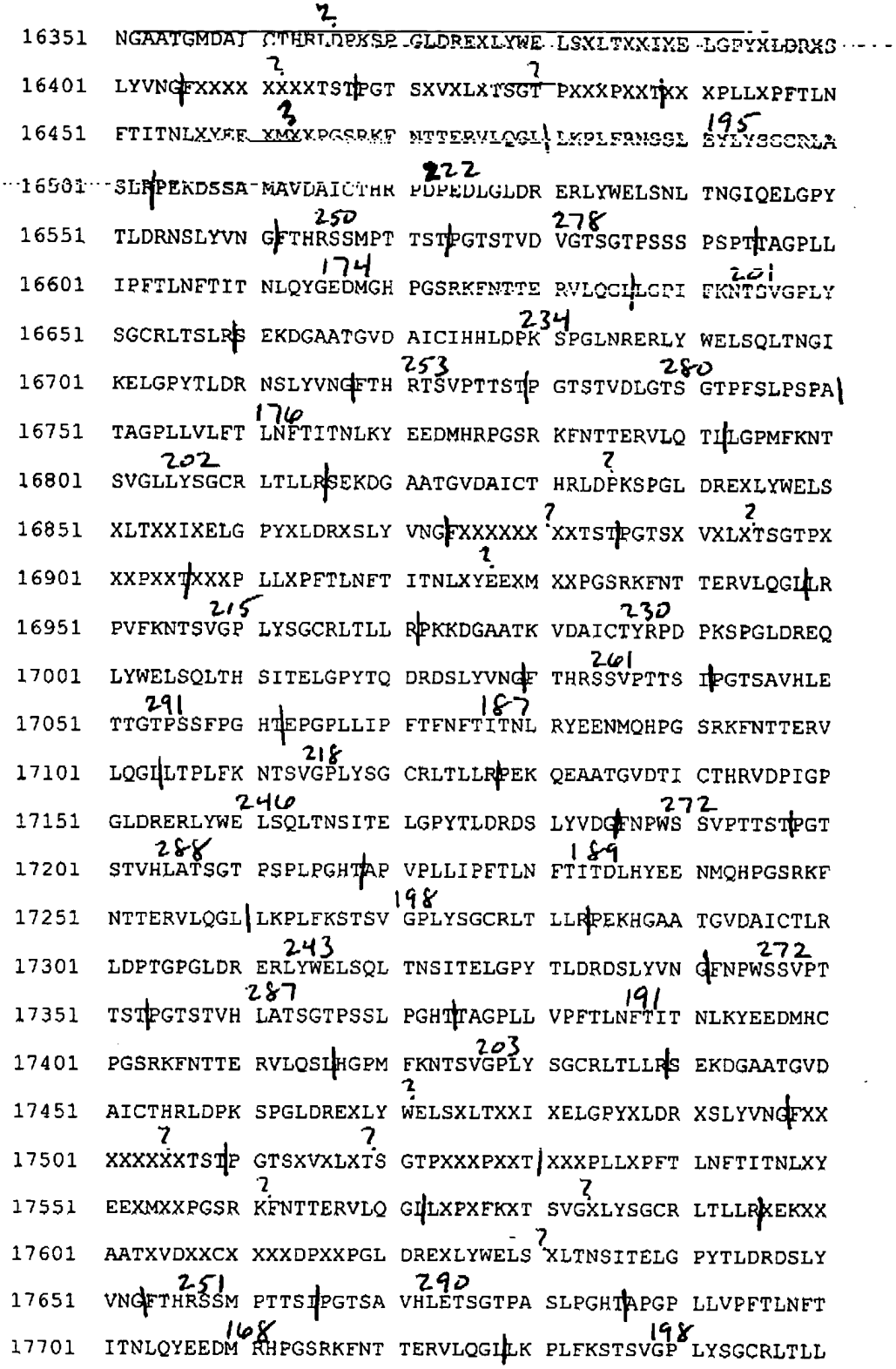

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17851 FTLNFTITNL XYEEXMXXPG SRKFNTTERV LQGLLXPXFK XTSVGXLYSG

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18151 PXXTXXXPLL XPFTLNFTIT NLXYEEXMXX PGSRKFNTTE RVLQGLLXPX

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18351 GLLTPLFKNT SVGPLYSGCR LTLLRPEKQE AATGVDTICT HRVDPIGPGL

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18701 CTLRLDPTGP GLDREXLYWE LSXLTXXIXE LGPYXLDRXS LYVNGFXXXX

18751 XXXXTSTPGT SXVXLXTSGT PXXXPXXTXX XPLLXPFTLN FTITNLXYEE

18801 XMXXPGSRKF NTTERVLQGL LXPXFKXTSV GXLYSGCRLT LLRXEKXXAA

18851 TXVDXXCXXX XDPXXPGLDR EXLYWELSXL TXXIXELGPY XLDRXSLYVN

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18951 NLQYEEDMHR PGSRKFNTTE RVLQGLLSPI FKNSSVGPLY SGCRLTSLRP

19001 EKDGAATGMD AVCLYHPNPK RPGLDREQLY CELSQLTHNI TELGPYSLDR

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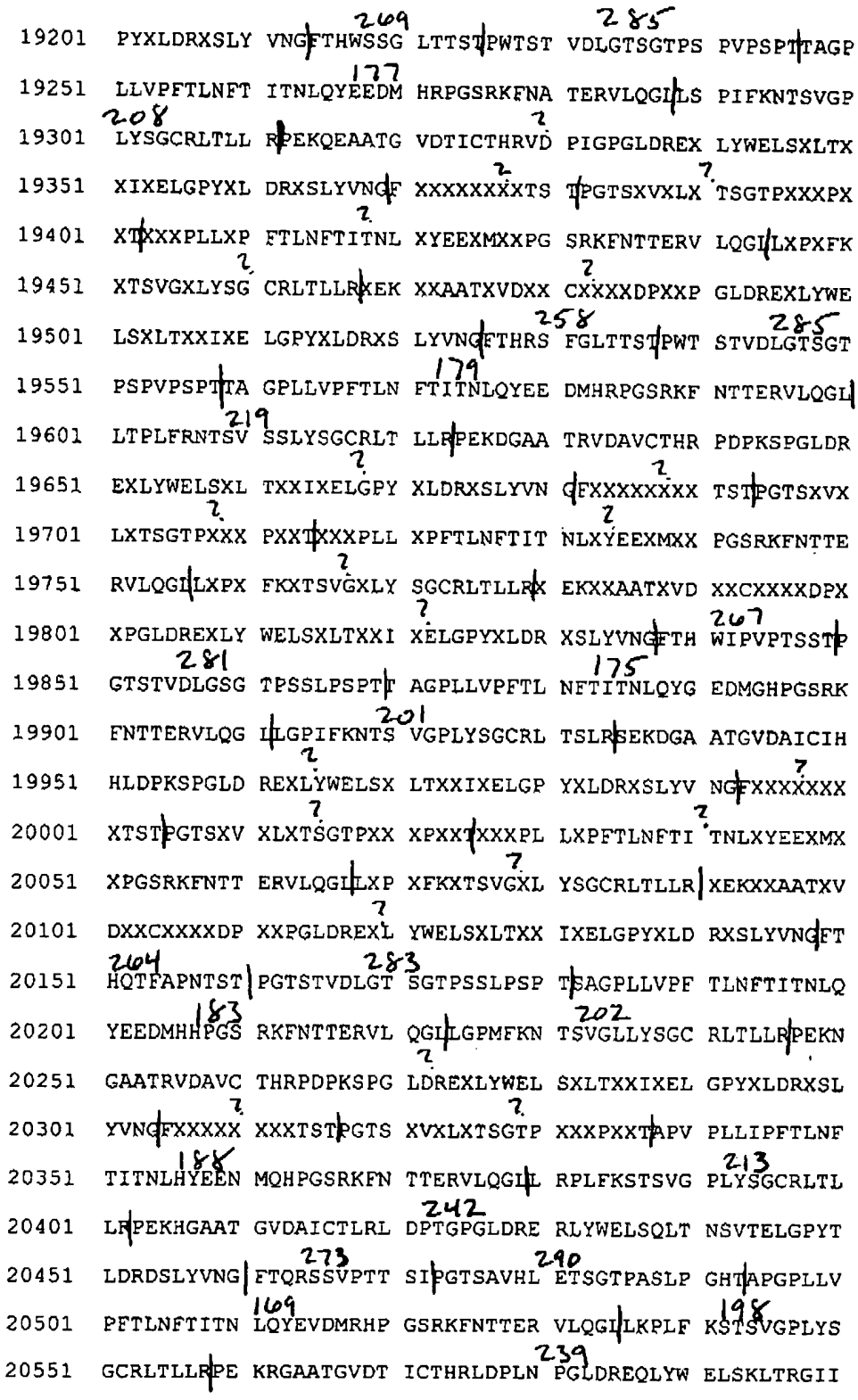

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20801  LPETTXXXPL LXPFTLNFTI TNLXYEEXMX XPGSRKFNTT ERVLQGLLKP
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21101  TMHLATSRTP ASLSGPTTAS PLLVLFTINF TITNLRYEEN MHHPGSRKFN
21151  TTERVLQGLL RPVFKNTSVG PLYSGCRLTL LRPKKDGAAT KVDAICTYRP
21201  DPKSPGLDRE QLYWELSQLT HSITELGPYT QDRDSLYNVG FTQRSSVPTT
21251  SVPGTPTVDL GTSGTPVSKP GPSAASPLLV LFTLNGTITN LRYEENMQHP
21301  GSRKFNTTER VLQGLLRSLF KSTSVGPLYS GCRLTLLRPE KDGTATGVDA
21351  ICTHHPDPKS PRLDREQLYW ELSQLTHNIT ELGHYALDND SLFVNGFTHR
21401  SSVSTTSTPG TPTVYLGASK TPASIFGPSA ASHLLILFTL NFTITNLRYE
21451  ENMWPGSRKF NTTERVLQGL LRPLFKNTSV GPLYSGSRLT LLRPEKDGEA
21501  TGVDAICTHR PDPTGPGLDR EQLYLELSQL THSITELGPY TLDRDSLYVN
21551  GFTHRSSVPT TSTGVVSEEP FTLNFTINNL RYMADMGQPG SLKFNITDNV
21601  MKHLLSPLFQ RSSLGARYTG CRVIALKSVK NGAETRVDLL CTYLQPLSGP
21651  GLPIKQVFHE LSQQTHGITR LGPYSLDKDS LYLNGYNEPG LDEPPTTPKP
21701  ATTFLPPLSE ATTAMGYHLK TLTLNFTISN LQYSPDMGKG SATFNSTEGV
21751  LQHLLRPLFQ KSSMGPFYLG CQLISLRPEK DGAATGVDTT CTYHPDPVGP
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